York Foundation Trust R&D Unit
SOP
Pharm/S104

Documenting, managing and reporting deviations.

(to be used in conjunction with Pharm/F107 – Deviation Assessment Form)

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Date:	25th February 2019
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	Signature:	Signed copy held by R&D Unit
	Date:	25th February 2019

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

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Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	23rd December 2015	-
2.0	25th March 2019	Change of author. Change of link to R&D website. Review to match updated form.

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1 Introduction, Background and Purpose

The purpose of this SOP is to ensure that the Pharmacy clinical trials team act upon and record any planned or unplanned deviations appropriately. It is important we follow the process described in this SOP to ensure a quality service is delivered and corrective action is taken so patient safety is ensured. Examples of deviations include unapproved changes to documents or equipment, and deviation from trial protocols or SOPs.

If a deviation is classed as a serious breach of protocol or Good Clinical Practice (GCP) you must report this according to R&D/S04 –Breaches of GCP or the study protocol. The definition of a 'serious breach' is 'A routine or systematic deviation from the protocol which is likely to affect to a significant degree: the safety or physical or mental integrity of the subject of the trial or the scientific value of the trial' (Medicines for Human Use Clinical Trial Regulations 2004)'.

If a deviation does not result in harm to the study subject(s) or significantly affect the scientific value of the reported results of the study this must be documented but it will not be classed as a serious breach.

Please note that quality exceptions (deviations) occurring in the Aseptic Unit will need to be processed according to the Aseptic standard reporting procedure.

2 Who Should Use This SOP

This SOP should be followed by all members of the pharmacy clinical trials team.

3 When this SOP Should be Used

This SOP should be used when planned or unplanned deviations occur.

4 Procedure(s)

1. All deviations must be reported immediately to the most senior member of the clinical trials team on duty
2. Where there is a requirement to take immediate corrective action to ensure patient safety, verbal agreement of action must be sought from a Pharmacist to ensure timely and appropriate measures are implemented, and Pharm/F107 can be completed retrospectively.
3. All deviations of GCP or protocol must be clearly and systematically documented, in order for appropriate corrective and preventive actions to be taken obtain and complete all sections of Pharm/F107 – Deviation Assessment Form
4. An assessment should be made by the Clinical Trials Manager (or designated individual) as to whether the breach is serious or not. If necessary advice should be sought by contacting the R&D Unit (refer to R&D/S04).
5. Ensure all corrective and preventative actions are taken (as appropriate).

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6. All suspected **serious** breaches must be reported to:
    - The sponsor of the study within 24 hours of the breach being identified.
    - The relevant members of the R&D department within 24 hours of the breach being identified.
    - The relevant members of the research team and PI within 24 hours of the breach being identified.
    - For studies hosted by the Trust these must be notified directly to the trial manager of the study , and at the same time, the Head of R&D (or delegate) must also be notified if a suspected serious breach has occurred within the Trust (refer to R&D/S04).

    If the deviation is not deemed as serious then the relevant people should be informed at the earliest convenience.

7. If the deviation involves a process external to Pharmacy clinical trials (e.g. Aseptic Unit, Pharmacy Stores and Distribution, Satellite Unit) then staff may process this according to their own SOP's and forms. If appropriate, Pharmacy clinical trial staff should obtain a copy of any relevant documentation and attach to our Deviation Assessment Form.
8. File Pharm/F107 in the Deviation Assessment Form file and attach copies of any correspondence relating to the deviation with this form.
9. The Pharmacy Clinical Manager (or designated individual) must review individual deviations, in a timely manner, taking a risk based approach to ensure they are closed (i.e. all corrective and preventative actions have been implemented).
10. If a patient has come to harm or could of potentially encountered harm, then a DATIX must be completed – see the Trust intranet page for DATIX reporting.
11. Feedback must be given to individuals and department/s as appropriate. File notes should be completed (if appropriate) detailing the deviation, accompanied by any relevant correspondence and filled in the appropriate section of the pharmacy site file.

5 Related SOPs and Documents

Pharm/F107 - Deviation Assessment Form

R&D/S04 –Breaches of GCP or the study protocol

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